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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/551,883

11/29/2005

Ask Puschl

434-US-PCT

6788

45821 7590 10/06/2008
LUNDBECK RESEARCH USA, INC.
ATTENTION: STEPHEN G. KALINCHAK, LEGAL
215 COLLEGE ROAD
PARAMUS, NJ 07652

EXAMINER

CHANG, CELIA C

ART UNIT

PAPER NUMBER

1625

MAIL DATE

DELIVERY MODE

10/06/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/551,883	Applicant(s) PUSCHL ET AL.	
	Examiner Celia Chang	Art Unit 1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 August 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 17-26 and 29-52 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 17-26 and 29-52 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>12/12/07(6), 10/24/06, 5/8/06, 1/17/06</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. A preliminary amendment was filed by applicants dated Aug. 29, 2008.
Claims 1-16, 27-28, 35-36 have been canceled. Claims 17-26, 28-34, 37-52 are pending.
2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 17-26, 28-34, 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ong US 4,198,419 supplemented with CA 93:71569.

Ong et al. disclosed RN 74442-94-7 as synthetic intermediate for making the claimed compounds. This species is an N-protected compounds of the instant claim 38, although the 14th compound has been deleted, the currently amended multiple substituted compounds are generically taught by '419. N-protection and its hydrolyzed modification are considered prima facie obvious in the chemical art especially variations of protected compounds were disclosed by the reference for making the piperidine free base.

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in

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section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 17-26, 28-34, 37, 39-52 are rejected under 35 U.S.C. 102(e) as being anticipated by Rubland et al. US 7,138,407, US 7,144,884, or US 7,148,238 (all cited on 1449).

Rubland et al. '407, '884, '238 disclosed the 4-[2-(4-methylphenylsulfanyl)-phenyl]-piperidine at col. 4 line 38. The same reference also disclosed small genus of compounds **explicitly** delineated at col. 4 lines 7-38 among which the 4-[2-(4-Chloro-phenylsulfanyl)-phenyl]-piperazine at line 21. The instant claims are anticipated by the reference because the classes of the reference were sufficiently limited and well delineated with modification of two species to arrive at the species of the instant claims. In re Arkley 172 USPQ 524, In re Schaumann 197 USPQ 5, In re Petering 133 USPQ 275, Ex Parte A 17 USPQ2d 1716.

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 17-26, 28-34, 37-52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rubland et al. US 7,138,407, US 7,144,884, or US 7,148,238.

Rubland et al. '407, '884, '238 disclosed the 4-[2-(4-methylphenylsulfanyl)-phenyl]-piperidine at col. 4 line 38. The same reference also disclosed small genus of compounds explicitly delineated at col. 4 lines 7-38 among which the 4-[2-(4-Chloro-phenylsulfanyl)-

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phenyl-piperazine at line 21 and 23 other compounds clearly delineated the variation of mono, or di- or tri-substitution on the phenylsulfanylphenyl system. One having ordinary skill in the art in possession of the Rubland et al. reference including the well delineated species and the generic teaching of formula I would be motivated to pick and choose any of the combination of the genus of the issued patent guided by the well guided species on col. 4. In absence of unexpected results, there is nothing unobvious in picking some among many. In re Lemin 141 USPQ 814.

5. Claims 17-26, 28-34, 37-52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rubland et al. US 6,699,864.

Rubland et al. '864, col. 7, formula III, disclosed the instantly claimed compounds as intermediates for making final products. Since US 7,148,238, US 7,138,407 or US 7,144,884 evidenced that the intermediates would have separate utility in addition to the utility of being starting material for products of US 6,699,864, one skilled in the art in possession of the Rubland et al. formula III is tantamount to be in possession of the instant claims generically and rendered the more limited subgenus or species obvious.

6. US patent No. 6,699,864 disclosed the instant claimed subject matter (see col. 7, formula III) and fully enabled the intermediates. The US 6,699,864 has a common assignee as the instant application but did not claim the disclosed intermediates. Applicants are urged to follow the instruction of MPEP 715.01(b)-(c) to provide evidence in the record that the issued patent derived the invention from the instant inventor and that the issued patent and instant claims are commonly owned or subject to common obligation at the time the invention was made.

7. Claims 17-26, 28-34, 37-52 rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-18 of U.S. Patent No. 7,148,238. Although the conflicting claims are not identical, they are not patentably distinct from each other because the issued claims contain overlapping compounds with the instant claims. The overlapping compounds are obvious variations of the mix and match combination of substituents on the phenylthiophenyl ring system (see for example the proviso conditions of the instant claims),

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therefore, renders the non-overlapping scope prima facie obvious since they differ in explicit/nonexplicit combination of Markush elements.

8. Claims 17-26, 28-34, 37-52 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-18 of US of US Patent No. 7,138,407 or claims 1-29 of US Patent No. 7,144,884 in view of Rubland et al. US 6,699,864.

Claims 1-18 of US of US Patent No. 7,138,407 or claims 1-29 of US Patent No. 7,144,884 are drawn to piperazinyl or dihydropyridinyl ring instead of the instant piperidinyl ring compounds with similar substitution of a phenylthiophenyl at the 4-position. The optional choices of piperazine, dihydropyridine as an alternative of piperidine ring is conventionally disclosed by the '864 patent, thus, are obvious alternative choice for one having ordinary skill to pick and choose. In absent of unexpected result, there is nothing unobvious in picking an alternative choice among the conventional class of compounds.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

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Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

9. Claims 17-26, 28-34, 37-52 are directed to the same invention as that of US 7,138,407, US 7,144,884, or US 7,148,238. As it was delineated supra the instant claims are anticipated by the reference because the classes of the reference were sufficiently limited and well delineated with modification of two species to arrive at the species of the instant claims. In re Arkley 172 USPQ 524, In re Schaumann 197 USPQ 5, In re Petering 133 USPQ 275, Ex Parte A 17 USPQ2d 1716. Thus, the instant claims are drawn to the “same” invention as the issued patents. The issue of priority under 35 U.S.C. 102(g) and possibly 35 U.S.C. 102(f) of this single invention must be resolved.

Since the U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP Chapter 2300), the assignee is required to state which entity is the prior inventor of the conflicting subject matter and provide evidence that the instant and copending compounds are commonly owned at the time the invention was made. A terminal disclaimer has no effect in this situation since the basis for refusing more than one patent is priority of invention under 35 U.S.C. 102(f) or (g) and not an extension of monopoly.

Failure to comply with this requirement will result in a holding of abandonment of this application.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celia Chang, Ph. D. whose telephone number is 571-272-0679. The examiner can normally be reached on Monday through Thursday from 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet L. Andres, Ph. D., can be reached on 571-272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

OACS/Chang
Sept. 25, 2008

/Celia Chang/
Primary Examiner
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